

REMARKS

Claims 1-19 are pending and stand rejected. Applicants cancel claim 16 and amend independent claim 1 to clarify that the control unit is adapted to monitor and store dose-response information and to adjust the desired biochemical parameter in response to the monitored and stored information. Support for this amendment can be found throughout the specification and in the claims, for example at page 16, lines 20-26, and in claim 5. Applicants also amend independent claim 14 to include subject matter previously recited in cancelled claim 16, and to clarify that the control unit responds to the compiled data to create and adjust a treatment model. Support for this amendment can be found throughout the specification, for example, at page 10, lines 16-22, and page 16, lines 20-26. No new matter is added.

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Rejection Pursuant to 35 U.S.C. §102

Claims 1-19 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by each of U.S. Patent No. 6,442,413 of Silver, U.S. Publ. No. 2002/0138018 of Lange et al. (Lange), and U.S. Patent No. 5,730,125 of Prutchi et al. (Prutchi). The Examiner argues that each of these references discloses the drug delivery system and method substantially as claimed.

Applicants amend independent claims 1 and 14 to clarify that the control unit not only receives the sensor output signal and delivers a signal to the pump, but that it also monitors and stores dose-response information or data, and it responds to the stored data by adjusting the desired biochemical parameter (claim 1) or creating and adjusting a treatment model (claim 14). None of the cited references teaches or even suggests a drug delivery system or method in which the system tracks data and relies on that data to adjust the treatment parameters.

Silver discloses a sensor that is used to monitor glucose levels in a patient's blood, and an insulin pump that responds to the signal received from the sensor. Silver is specifically limited to a read and respond type system, wherein the glucose level is detected and the pump is directed to respond to the detected level. Silver does not teach or even suggest storing the sensed data, much less adjusting the treatment parameters in response to the stored data. Silver states that only two things can happen when the glucose level is outside of the normal physiological range (e.g. the desired parameter):

1. An audible, visible or tactile alarm may sound, so that the patient or physician may check the sensor with a home glucose monitoring kit . . . , and then take appropriate action such as administration of insulin or glucose.
2. The signal may be transmitted directly to an implantable insulin pump, which may administer insulin directly without requiring a response by the patient.

(Silver, Col. 22, lines 51-60.) Accordingly, Silver does not teach or even suggest storing the sensed data, and relying on that data to adjust the treatment parameters. In fact, it would not be necessary to rely on stored data to adjust the treatment parameters since the only goal of Silver is to maintain a patient's glucose levels. Claims 1-15 and 17-19 therefore distinguish over Silver.

Lange likewise does not teach or even suggest storing data and relying on the stored data to adjust treatment parameters. At Page 15, paragraph 207, Lange states that:

In order to regulate patient pain, the controller 146 automatically adjusts the medication amount by controlling the infusion pump 144 based on changes in patient pain level (as measured by the pain measuring device).

Accordingly, Lange is limited to detecting a signal, e.g., the patient's pain level, and responding to the sensed signal by delivering the necessary amount of a drug. Lange does not teach or even suggest relying on the stored data to adjust treatment parameters. Again, as stated above with respect to Silver, there would be no need to alter the system based on the stored data using Lange's device since the Lange's devise is merely used to control pain. Applicant's system and

device, on the other hand, can be used, for example, to track the progression of a disease over time and to response to any changes as needed.

Prutchi also fails to teach or even suggest the present invention. Prutchi discloses an implantable medical device that is coupled to sensors used to control and implement the operation of the device. Prutchi states that “the physiological parameters [] may be sensed by implantable device 10 and evaluated for use in stimulating the heart, providing a defibrillizing pulse or dispensing needed medication . . .” Prutchi does not suggest storing the sensed data, much less relying on the stored data to adjust the treatment parameters. Accordingly, Prutchi, like Silver and Lange, also fails to teach or even suggest the present invention, and therefore claims 1-19 represent allowable subject matter.

Applicants have provided a novel drug delivery system and method that can respond to a patient’s changing needs by processing and storing signals from an implanted sensor, and adjusting the treatment parameters based on the stored data. This is particularly advantageous because

treatments involving the system of the invention are dynamic; they vary from individual to individual, and disease to disease. The need for a particular drug or biological agent, and the dose of the agent required, will also vary with changing severity of a disease. For example, as a patient’s health improves, the drug or biological agent may be metabolized at a faster rate, so a higher dose would be required.

(Specification, Page 3, lines 17-23.) Thus, as the patient’s disease state changes, the system monitors these changes and the patient’s response to these changes, and the stored information is relied on to adjust the treatment parameters, e.g., “to determine a treatment model.” (Specification, Page 16, line 26.)

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-15 and 17-19 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: July 21, 2003


Lisa J. Michaud
Reg. No. 44,238
Attorney for Applicant(s)

NUTTER, MCCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2699
Tel: (617)439-2550
Fax: (617)310-9550

1229050.1